# IN THE UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

UNITED STATES	)
Petitioner,	) Civil Action No. 3:20-cv-00158
v.	) Judge Aleta A. Trauger
FRESENIUS MEDICAL CARE HOLDINGS, INC., et al.	) Magistrate Judge Jeffery S. Frensley
Respondents.	) )

# RESPONDENTS' ANSWER TO PETITION FOR SUMMARY ENFORCEMENT OF INSPECTOR GENERAL SUBPOENAS

Respondents Fresenius Medical Care Rx, LLC, Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius" or "Respondents") Answer the United States' Petition for Summary Enforcement of Inspector General Subpoenas ("Petition") (ECF 1) as set forth below. Respondents' response to the Petition is set forth more fully in its Opposition To Petition To Enforce Inspector General Subpoenas. To the extent any allegation in the Petition is not expressly admitted in this Answer, it is denied.

#### **Jurisdiction and Venue**

- 1. The allegations in this Paragraph are legal conclusions to which no answer is required. To the extent an answer is deemed required, Respondents admit only that Petitioner purports to bring this action under 28 U.S.C. §§ 1331 and § 1345 and the Inspector General Act of 1978, 5 U.S.C. App. 3 § 6(a)(4). Respondents deny that these statutes authorize the Petition, that any statute was violated, or that the Petition has any basis in fact or law. All allegations not specifically admitted herein are denied.
  - 2. The allegations in this Paragraph are legal conclusions to which no answer is

required. To the extent an answer is deemed required, Respondents deny that a proper basis of venue is the location of the Department of Health and Human Services Office of Inspector General's ("HHS-OIG") investigation or a location where Respondents are found or transact business. Respondents deny that a substantial part of the events or omissions giving rise the Petition—specifically, the creating and sending of privilege logs and document productions—occurred the Middle District of Tennessee. All allegations not specifically admitted herein are denied.

#### **Parties**

- 3. Respondents admit only that Petitioner is the United States of America.
- 4. Respondents admit that Respondents are Fresenius Medical Care Rx, LLC, Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Holdings, Inc.; that Fresenius Medical Care Pharmacy Services, Inc. is a privately held corporation, incorporated in Delaware that transacts business in Florida and other states; and that Fresenius Medical Care Holdings, Inc. is a privately held corporation, incorporated in New York, that transacts business in Tennessee and other states. (ECF 23-25.) All allegations not specifically admitted herein are denied.
- 5. Respondents admit that HHS-OIG Subpoena Duces Tecum with Control Numbers 17498, 17499, and 17500 were issued to Fresenius Medical Care Rx, LLC, Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Holdings, Inc., respectively, through Respondents' attorney. Respondents admit that HHS-OIG Subpoenas 17498, 17499, and 17500 purport to serve as the basis for this Petition. All allegations not specifically admitted herein are denied.

### **Authority for and Issuance and Service of Subpoena**

- 6. Respondents lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the HHS-OIG investigation contained in this paragraph and, accordingly, deny the allegations in their entirety. Respondents deny they violated any statute regarding fraud and abuse of federal healthcare programs, billing federal healthcare programs or kickbacks. Respondents deny that any HHS-OIG investigation related to Respondents has any basis in fact or law. All allegations not specifically admitted herein are denied.
- 7. The allegations in this Paragraph are legal conclusions to which no answer is required. To the extent an answer is deemed required, Respondents admit that the Inspector General Act provides that each Inspector General, in carrying out the provisions of the Act, is authorized: "to require by subpoena the production of all information, documents, reports, answers, records, accounts, papers, and other data in any medium (including electronically stored information), as well as any tangible thing and documentary evidence necessary in the performance of the functions assigned by this Act, which subpoena, *in the case of contumacy or refusal to obey*, shall be enforceable by order of any appropriate United States district court...." 5 U.S.C.A. § APP. 3 § 6(a)(4) (emphasis supplied). All allegations not specifically admitted herein are denied.
- 8. Respondents incorporate their answer to Paragraph 5 regarding the HHS-OIG subpoenas. Respondents admit that HHS-OIG Subpoenas—which were hand-served in Waltham, Massachusetts—included requests related to certain policies and procedures, marketing, budgeting, compliance, claims data, patient records, electronic communications, and internal audits. All allegations not specifically admitted herein are denied.
  - 9. Respondents incorporate their answers to Paragraphs 5 and 6 regarding the HHS-

OIG subpoenas and investigation. Allegations in this Paragraph regarding the False Claims Act are legal conclusions to which no answer is required. Respondents deny they defrauded Medicare or Medicaid, or violated the False Claims Act. Respondents deny that any HHS-OIG investigation related to Respondents has any basis in fact or law. All allegations not specifically admitted herein are denied.

## Fresenius' Failure to Comply with HHS-OIG's Subpoenas

- 10. Respondents incorporate their answers to Paragraphs 6 and 9 regarding the HHS-OIG investigation. Respondents admit only their counsel conferred with the United States regarding their response to the HHS-OIG subpoenas. All allegations not specifically admitted herein are denied.
- 11. Respondents admit only that on October 22, 2018, they provided Petitioner a privilege log identifying documents withheld or redacted for privilege. All allegations not specifically admitted herein are denied.
- 12. Respondents admit only that on May 10, 2019, they provided Petitioner privilege logs revised as requested by Petitioner. All allegations not specifically admitted herein are denied.
- 13. Respondents admit only that on September 19 and 30, 2019, they provided Petitioner privilege logs revised as requested by Petitioner. All allegations not specifically admitted herein are denied.
- 14. Respondents admit only that the Petition seeks summary enforcement of the HHS-OIG subpoenas. All allegations not specifically admitted herein are denied.
- 15. Respondents deny that there is any basis in fact or law to award any relief to Petitioner.

AFFIRMATIVE AND OTHER DEFENSES

Without waiving general or specific denials herein or in its Opposition To Petition To

Enforce Inspector General Subpoenas, to the extent affirmative defenses should be pleaded,

Respondents assert the following affirmative and other defenses.

1. Except as expressly admitted herein, Respondents deny all allegations in the

Petition.

2. Respondents allege an affirmative defense, and here rely, on each and every

argument set forth in their accompanying Opposition To Petition To Enforce Inspector General

Subpoenas.

In asserting these affirmative defenses, Respondents are not assuming the burden to

establish any fact, proposition or element where the burden is properly imposed upon Petitioner.

WHEREFORE, Respondents pray that this Court dismiss the Petition, enter judgment

against Petitioners and for Respondents, award Respondents fees and costs incurred in this action,

and such further relief as the Court may deem just and proper.

Date: April 24, 2020

Respectfully submitted,

By: /s/ James F. Bennett

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Attorneys for Fresenius Medical Care Rx, LLC, Fresenius Medical Care Pharmacy Services, Inc., and Fresenius Medical Care Holdings, Inc.

### **CERTIFICATE OF SERVICE**

I hereby certify that on this 24th day of April 2020, I electronically filed the foregoing Respondents' Answer To Petition For Summary Enforcement Of Inspector General Subpoenas with the Clerk of Court using the CM/ECF system, which sent notification of the filing to all counsel of record, including the following:

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